DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1236d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 10, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 58

Dr. F. Abel Ponce de Leon
Chair, Department of Animal Science
University of Minnesota
305B Haecker Hall
1364 Eckles Avenue
St. Paul, Minnesota 55108

Dear Dr. Ponce de Leon:

On March 2, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your animal feed manufacturing operation located at the Agricultural Experiment Station, 1605 - 160th Street West, Rosemount, MN. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000, "Animal Proteins Prohibited in Ruminant Feed" (21 CFR 589.2000). The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or distributed by this facility to be misbranded within the meaning of Section 403(f) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found a failure to label your products with the required cautionary statement, "Do Not Feed to Cattle or Other Ruminants." The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

You should take prompt action to correct these violations and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

Please provide this office a written update within 15 working days of receipt of this letter with the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/ccl

Enclosure: FDA Small Entities Compliance Guide, 21 CFR 589.2000

xc: Dana M. Souther
Administrative Director,
Department of Animal Science
University of Minnesota
305A Haecker Hall
1364 Eckles Ave.
St. Paul, MN 55108

Jack Otis
Feed Mill Supervisor,
Rosemount Agricultural Experiment Station
University of Minnesota
1605 – 160th Street West
Rosemount, MN 55068